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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/524,357

02/14/2005

Robert Rieben

3023-108

6328

46002 7590 10/07/2008

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EXAMINER

DICKINSON, PAUL W

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

10/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/524,357 | Applicant(s) RIEBEN ET AL. | |
| | Examiner PAUL DICKINSON | Art Unit 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restriction

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted:

Group I, claims 1-11 and 14, drawn to a polyacrylamide conjugate.

Group II, claims 12, drawn to a method for inhibiting P-selectin *in vitro* comprising administering a polyacrylamide conjugate to a cell in a P-selectin inhibiting effective amount..

Group III, claims 13 and 15, drawn to a method for protecting endothelial cells from complement-medicated cytotoxicity comprising administering a polyacrylamide conjugate to said cells *in vitro*.

Group IV, claim 16, drawn to a method for preventing and/or treating inflammatory reactions toward endothelial cells comprising administering to an animal in need thereof a polyacrylamide conjugate in an inflammatory reactions towards endothelial cells preventing and/or treating amount.

Group V, claims 17 and 19, drawn to a method for preventing ischemia/reperfusion damage comprising administering to an animal in need thereof a polyacrylamide conjugate in an ischemia/reperfusion damage preventing amount.

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Group VI, claim 18, drawn to a method for the treatment of cardiac or brain infarction comprising administering to an animal in need thereof a polyacrylamide conjugate in a cardiac or brain infarction treating amount.

Group VII, claims 20 and 21, drawn to a method for acute vascular rejection reactions comprising administering to an animal in need thereof a polyacrylamide conjugate in an acute vascular rejection reaction preventing amount.

Group VIII, claim 22, drawn to a method for safe-keeping-of life donor organics for use in transplants comprising providing a solution comprising a polyacrylamide conjugate and adding a life donor organ to said solution.

Group IX, claim 23, drawn to a method for preventing a rejection reaction during allogeneic and xenogeneic islet transplantation comprising administering to an animal in need thereof a polyacrylamide conjugate in a rejection reaction during allogeneic or xenogeneic islet transplanation preventing amount.

Group X, claim 24, drawn to a method for preventing and/or treating an HIV infection comprising administering to an animal in need thereof a polyacrylamide conjugate in an HIV infection preventing and/or treating amount.

Group XI, claim 25, drawn to a method for preventing and/or treating severe sepsis or septic shock comprising administering to an animal in need thereof a polyacrylamide conjugate in a severe sepsis or spetic shock preventing and/or treating amount.

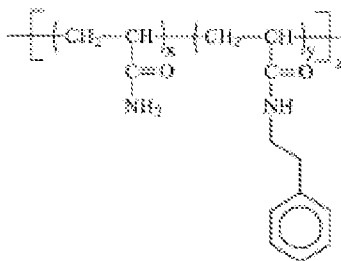
Group XII, claim 26, drawn to a method for preventing and/or treating acute respiratory distress syndrome comprising administering to an animal in need thereof a

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polyacrylamide conjugate in an acute respiratory distress syndrome preventing and/or treating amount.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The common technical feature of the above groups is a polyacrylamide conjugate as disclosed in Claim 1. This element cannot be a special technical feature under PCT Rule 13.2 because it is not novel. Abu-Sharkh et al (Abu-Sharkh et al, Solution and Interfacial Behavior of Hydrophobically Modified Water-Soluble Block Copolymers of Acrylamide and N-Phenethylacrylamide, Journal of Applied Polymer Science, 2001, 82, 467-476) discloses an amphiphilic copolymer of acrylamide and N-phenethylacrylamide:



(see Figure 1; Results and Discussion). The N-phenethylacrylamide is present in 2-3 molar %. The amphiphilic copolymer is used in a variety of commercial applications (see Introduction). The presence of the hydrophobic N-phenethylacrylamide gives the copolymer improved thickening properties (see abstract; Conclusions). Above a certain percentage of the hydrophobic monomer, the polymers aggregate together and exhibit thickening properties equivalent to higher molecular weight polymers (see Introduction).

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Such copolymers have use as industrial thickeners (see *ibid*). Abu-Sharkh et al fails to disclose an embodiment wherein the N-phenylethylacrylamide is present in 20-100%.

Abu-Sharkh et al discloses 2-3 molar % of N-phenylethylacrylamide, but suggests exploring higher concentrations. Thus, it would have been obvious to one of ordinary skill in the art to increase the molar percent of N-phenethylacrylamide, through routine experimentation, to optimize the viscosity of the copolymer for application as an industrial thickener. In this way, it would be obvious to find the instant range of 20-100 molar %.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

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be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul W. Dickinson whose telephone number is 571-270-3499. The examiner can normally be reached on Mon-Thur 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 217-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul W. Dickinson
Examiner
Art Unit 1618

September 29, 2008